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09/471,255	12/23/1999	JOSEE HAMEL	55190-012	7195

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MCDERMOTT WILL & EMERY
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/471,255	Applicant(s) Hamel et al
	Examiner Portner	Art Unit 1645

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 7, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16 and 18-37* is/are pending in the application.

4a) Of the above, claim(s) *1-15, 21-24, 26-31, 33, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16, 18-20, 25, 32, 34, and 35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-16 and 18-37* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *interview summary*

DETAILED ACTION

Claim 17 has been canceled.

New Claims 32-37 have been added.

Claims 1, 18-20 and 25 have been amended.

Claims 16, 18-20, 25, 32, and 34-35 recite the elected invention and are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

2. The information disclosure statements filed June 7, 2002 has been considered prior to this action.

Allowable Subject Matter

3. Claims 18-20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and the Office Action in paper number 17.

4. None of the claims recite the critical functional limitations disclosed in the instant specification for induction of a protective immune response, wherein an immune response induced to the hyper variable region at the C-terminal of the polypeptide is protective. The claimed polypeptides are not required to comprise the critical amino acid sequence that defines the polypeptides asserted, disclosed utility as a protective antigen.

Election/Restriction

5. Newly submitted claims 32-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 32-37 recite non-elected inventions directed to independent and distinct inventions, each SEQ ID No defines a molecule evidence a different structure, function and effect. These SEQ ID Nos are: SEQ ID NO 4, 10, 14, 16, 55, 58, 64, 60, 62-69,71-75, and 77-79; as well as fragments, and polypeptides that evidence 95% sequence identity with the recited polypeptides. Claim 33 is directed to a vaccine composition that is defined by the combination of a plurality of SEQ ID Nos not previously examined and is not limited to a composition that only comprises SEQ ID NO 2.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Applicant's election with traverse of Group II, (claims 16-20 and 25), SEQ ID NO 2 in Paper No. 16, dated September 19, 2001 was acknowledged and made Final. Prior art was made of record that anticipated the claimed invention. No additional species or distinct inventions were required to be searched or examined. Claims 16-20 and 25 which recite additional SEQ ID Nos, to include the newly added recitation of the phrase "or a combination thereof", set forth non-elected inventions.

Objections/Rejections Withdrawn

7. The disclosure objected to because of informalities, in light of the amendment of the Specification to obviate the minor informalities.

8. Claim 16 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "an amino acid sequence chosen from SEQ ID NO 2", in light of the amendment of the claim to delete this phrase.

9. Claim 16 rejected under 35 U.S.C. 112, second paragraph for not reciting a polypeptide of any size, that is not required to have any biological function, in light of the deletion of the phrase "or fragments, analogs, or derivatives thereof"from the claim and with reference to SEQ ID No 2.

10. Claim 17 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "An isolated polypeptide capable of generating antibodies having binding specificity for a second polypeptide", in light of the cancellation of the claim.

11. Claim 17 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "capable of generating antibodies having binding specificity for a second polypeptide", in light of the cancellation of the claim.

12. Claim 18 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "An isolated polypeptide having an amino acid sequence chosen from SEQ ID NO 2", in light of the claim having been amended to delete the phrases "chosen from" and "or fragments, analogs or derivatives thereof" from the claim.

13. Claim 19 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "wherein the N-terminal Met residue is deleted", in light of the amendments of both claims 18 and 19 to clarify the invention as being directed to SEQ ID NO 2 which has a "methionine" an "secretory amino acid sequence.

14. Claim 19 rejected under 35 U.S.C. 112, second paragraph for reciting the abbreviation "Met", in light of the amendment of the claim to define the abbreviation in the claims.

15. Claim 20 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "wherein the secretory amino acid sequence is deleted", in light of the amendment of claim 18 to no longer recite the phrase "or fragments, analogs or derivatives thereof">

16. Claim 25 rejected under 35 U.S.C. 112, second paragraph in light of the claim having been amended to be an independent claim.

17. Claims 16-20, rejected under 35 U.S.C. 112, first paragraph (vaccine scope of enablement), in light of the amendment of claim 25 to no longer depend from claims 16-20.

Rejections Maintained

18. Claim 16, 18-20 and 25 rejected under 35 U.S.C. 112, second paragraph for reciting non-elected inventions. Amendment of the claims to recite the elected could obviate this rejection.

19. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, (as previously applied to claim 16, page 10, paragraph 11, paper number 17), for reciting the phrase "an amino acid sequence of SEQ ID Nos 2", which is a phrase equivalent to "an amino acid sequence chosen from", as the claimed isolated polypeptide is only required to have an amino acid sequence of SEQ ID No 2. What is sequence of the polypeptide? What is the size and function the claimed polypeptide? The meets and bounds of the claim are unclear.

20. Claims 16, 25, 32,34-35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility, for reasons of record in paper number 17, paragraph 7.

21. Claims 16, 25,32, and 34-35 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled

in the art clearly would not know how to use the claimed invention, , for reasons of record in paper number 17, paragraph 8.

22. Claims 16, 25,32, and 34-35 are rejected under 35 U.S.C. 112, first paragraph (*written description*), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in paper number 17, paragraph 12, as previously applied to claims 16-20 and 25.

23. Claim 32 is rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930,(Human Genome Sciences, May 7, 1998, SEQ ID NO 182, 56 and 66), as previously applied to claims 16-20 and 25, for reasons of record in paper number 17, paragraph 15.

Response to Amendment

24. The Declaration of Dr. Josee Hamel under 37 CFR 1.132 filed June 7, 2002 is insufficient to overcome the rejection of claims 16, 25,32, and 34-35 based upon 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph (written description and scope of enablement) as set forth in the last Office action because: The Declaration is directed to polypeptides that have "at least 99% sequence similarity" and the claims are directed to "at least 95% sequence identity". Applicant's arguments are not commensurate in scope with the instantly claimed invention. Specific embodiments are argued and evidence is provided for specific sequences which is not commensurate in scope with the instantly claimed invention which does not require the claimed

polypeptide to comprise the critical component of the C-terminal hyper variable region amino acid sequence which was taught as, and was shown to induce a protective immune response in vivo. The claimed polypeptides may evidence changes in any region, and need not comprise the essential epitopes that induce a protective immune response.

Response to Arguments

25. The rejection of claims 16, 25,32, and 34-35 under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility are asserted to have utility as a marker of Streptococcus infection, are immunogenic and induce the production of monoclonal antibodies and were shown to induce a protective immune response.

26. It is the position of the examiner that the claimed polypeptides are not required to evidence any of the asserted functional limitations. None of the claims recite the essential hypervarible region which was taught to be essential for the induction of a protective immune response. A polypeptide that has about 50 amino acids changed relative to the reference sequence (SEQ ID NO 2 has 1039 amino acids X 0.95% = 52 amino acid have been changed or deleted or inserted). No conserved biological function is required for the claimed polypeptides. Applicant's arguments are not commensurate in scope with the claimed invention. Amendment of the claims to recite the presence of the critical C-terminal hyper variable region epitopes for the induction of a protective immune response could obviate this rejection.

27. The rejection of claims 16, 25,32, and 34-35 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, is traversed as evidencing utility based upon the data presented in the instant specification and discussed in the Declaration submitted by Dr. Josee Hamel.

28. It is the position of the examiner that Applicant's arguments, and Dr. Josee Hamel's Declaration are not commensurate in scope with the instantly claimed invention. None of the claims recite any functional limitation to set forth the polypeptides as evidencing the critical characteristics asserted as defining a patentable utility for the polypeptides.

29. Claims 16, 25,32, and 34-35 rejected under 35 U.S.C. 112, first paragraph,(*written description)* as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is traversed on the grounds that the skilled practitioner can envision the detailed chemical structure of the encompassed polypeptides.

30. It is the position of the examiner that the claims are directed to amino acid sequences that encode polypeptides that correspond to sequences from other sources, mutated sequences, sequences that have a recited degree of identity (similarity, homology), analogs and derivatives of

SEQ ID No 2. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483,. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.)

With respect to the fact that the claims now recite 95% sequence identity, it is the position of the examiner that none of the claimed polypeptide are required to evidence any specific biological activity and may evidence changes up to 52 amino acids at any location. The source and the biological activity of the claimed polypeptides is not recited in the claims. The critical characteristics and polypeptides argued are recited in the claims other than SEQ ID No 2. The written description rejection made it clear that SEQ ID No 2 has been clearly described, but did not provide written descriptive support over the full scope of the claimed genus of polypeptides.

31. The rejection of claims 25, 34-35 under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for the production of a polypeptide consisting of SEQ ID No 2 and use of the polypeptide for the induction of a protective immune response when combined with

QuilA, and immunogenic fragments for the induction of antibodies to detect SEQ ID NO 2, does not reasonably provide enablement for the use of any polypeptides that only shares 95 % sequence identity with of SEQ ID NO 2, is asserted to have been enabled by the instant specification and can be combined with any adjuvant.

32. It is the position of the examiner that the claimed vaccines do not require the polypeptide to be combined with an adjuvant, but may be combined with a carrier or diluent. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

It is also the position of the examiner that the claimed polypeptides are not required to evidence the critical functional characteristic of being immunogenic and to comprise the hyper variable region which induces a protective immune response, as well as are not required to comprise an adjuvant that induce an enhanced immune response.

33. The rejection of claim 32 under 35 U.S.C. 102(a) as being anticipated by WO98/18930,(Human Genome Sciences, May 7, 1998, SEQ ID NO 182, 56 and 66), as previously applied to claims 16-20 and 25, is traversed on the grounds that the polypeptide of the prior art lacks immunity inducing capability.

34. It is the position of the examiner that none of the claimed polypeptides are required to comprise the essential C-terminal hyper variable region without any changes in the epitopes that induce the protective immune response argued. None of the polypeptides which share less than sequence identity of 100% are required to be immunogenic. The amino acid sequence of SEQ ID No 2 that the claimed polypeptide comprises "having", is not limited to any specific sequence that

is immunogenic. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

New Claims/New Claim Limitations/New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

35. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

36. Claims 19-20 (amended claims) and 34-35 (new claims) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19-20 depend from claim 18 are directed to polypeptides that are smaller in size than SEQ ID No 2. Fragments of SEQ ID No 2 are recited in claims 19-20, and thus increase the scope of claim 18 from which they depend which no longer recites the word "fragments". Claims 19 and 20 are not further limiting of claim 18.

Claims 34-35 depend from claim 25 and are directed to polypeptides that are smaller in size than SEQ ID No 2. Fragments of SEQ ID No 2 are recited in claims 34-35, and thus increase the scope of claim 25 from which they depend, which no longer recites the word "fragments". Claims 34 and 35 are not further limiting of claim 25.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

September 3, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600